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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,079	08/01/2006	Edith Sorensen	P30006	3993
7055 7590 08/03/2011 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER KENNEDY, NICOLETTA				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
08/03/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/582,079	SORENSEN, EDITH
	Examiner	Art Unit
	NICOLETTA KENNEDY	1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-21 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-15 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____ |
|---|--|

DETAILED ACTION

Status of Claims

Claims 1, 4-21 and 24-29 are currently pending. Claims 16-21 are withdrawn as drawn to a non-elected group.

Priority

This application, filed June 8, 2006, is a national stage entry of PCT/EP04/13963, filed December 8, 2004. PCT/EP04/13963 is a continuation in part of PCT/EP03/13873, filed December 8, 2003.

The examiner acknowledges Applicant's statement that PCT/EP03/13873 entered the US stage and was given the application number 10/582,223. However, US application 10/528,223 is not part of the lineage of the instant case and as such, has not been included in the priority recitation above.

Withdrawn Rejections

The rejections of record are withdrawn in view of Applicant's arguments and amendments.

New Rejections

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1, 4, 6, 8 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668) (pub. June 5, 1997) in view of Georgiades (US 2002/0061282) (pub. May 23, 2002).**

Regarding claims 1, 3-4, 6, 8, 11-13 and 22, Tame-Said teach a toothpaste and mouthwash in tablet (lozenge) form which dissolve in the mouth when contacted with saliva (abstract). The lozenge is comprised of 18 mg ascorbic acid (5.2% by weight), 50 mg sodium bicarbonate (14.49% by weight), 40 mg tricalcium phosphate (11.59% by weight), 17 mg sodium lauryl sulfate, 70 mg arabic gum (water soluble lozenge base) and 150 mg natural sweetness and flavoring agents (abstract). Tricalcium phosphate is identified as a polishing and bleach agent (p. 5). Sodium bicarbonate is identified as an effervescent and whitening product (p. 6).

However, Tame-Said fail to teach that calcium pyrophosphate is the polishing agent used in the tablet or that the amount of polishing agent may be modified. Georgiades cures these deficiencies.

Georgiades teaches a tooth-whitening composition that can be in the form of a lozenge (abstract). The lozenge can contain polishing materials, including calcium

pyrophosphate and tricalcium phosphate, from about 1 to about 99% by weight (para. 0037).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Tame-Said with those of Georgiades to have substituted calcium pyrophosphate for tricalcium phosphate. One would have been motivated to do so because both tricalcium phosphate and calcium pyrophosphate are known polishing materials used in the dentifrice art in lozenges and Tame-Said teaches the use of tricalcium phosphate, a polishing agent, in the lozenge.

Regarding claims 1, 3 and 22, MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, Georgiades teach that it is known in the dentifrice art to have polishing agents present from about 1-99% by weight. It thus would have been *prima facie* obvious to a person of ordinary skill in the art to manipulate the amount of polishing agent present in the lozenge because it is known in the art that the amount of polishing agent may be varied.

4. **Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (abstract, WO 97/19668) (pub. June 5, 1997) in view of Georgiades (US 2002/0061282) (pub. May 23, 2002) as applied to claims 1, 4, 6, 8 and 11-13 above, and further in view of Holme et al. (US 6,685,916) (filed Oct. 31, 2002.**

The combination of Tame-Said and Georgiades teach each limitation of claim 1 but fail to teach that the lozenge may be sugarless, comprises an encapsulated agent, or is in the form of a hard-boiled lozenge. Holme et al. cure these deficiencies.

Regarding claim 5, Holme et al. teach a composition for removing stains from dental surfaces. The composition may be a confectionary including lozenges (column 3, lines 47-53). The sweetener used in the confectionary may comprise sugar or be sugarless and instead use sugarless sweeteners such as sorbitol, mannitol, xylitol and maltitol (column 10, lines 33-41 and column 12, lines 9-15).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Tame-Said and Georgiades with those of Holme et al. to substitute sugarless sweetener for sugar in the composition. One would have been motivated to do so because using sugarless sweeteners reduces the amount of calories in the lozenge and does not contribute to the formation of dental plaque.

Regarding claim 10, Holme et al. teach that the composition may comprise encapsulated peroxide (claims 1 and 27). The peroxide is the active ingredient in the composition (abstract). It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have encapsulated the active ingredient of Tame-Said to prevent premature degradation of the active and to control the release rate of the active (Holme et al., column 4, lines 60-67).

Regarding claim 15, Holme et al. teach that the confectionary may be hard-boiled (column 12, line 21). It would have been prima facie obvious to hard-boil the lozenge

because this is a known method of making a confectionary in the dentifrice art with predictable results (Holme et al., column 12, lines 1-30).

5. Claims 7, 9 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (abstract, WO 97/19668) (pub. June 5, 1997) in view of Georgiades (US 2002/0061282) (pub. May 23, 2002) as applied to claims 1, 4, 6, 8 and 11-13 above, and further in view of Witt et al. (US 6,350,438).

The combination of Tame-Said and Georgiades teach each limitation of claims 1 and 6 but fail to teach that the amount of sodium bicarbonate may be modified. Witt et al. cure this deficiency.

Regarding claims 7, 9 and 24-25, Witt et al. teach topical oral compositions which may in the form of lozenges (abstract). The composition may comprise sodium bicarbonate in an amount of from about 0.5 to about 30% (column 15, lines 44-53). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Tame-Said and Georgiades with those of Witt et al. to adjust the amount of sodium bicarbonate used in the lozenge because Witt et al. teach that it is known in the lozenge art to have sodium bicarbonate present from about 0.5 to about 30% by weight.

6. Claims 11, 14 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (abstract, WO 97/19668) (pub. June 5, 1997) in view

of Georgiades (US 2002/0061282) (pub. May 23, 2002) as applied to claims 1, 4, 6, 8 and 11-13 above, and further in view of Majeti et al. (US 6,682,722) (filed Sept. 3, 2002).

The combination of Tame-Said and Georgiades teach each limitation of claims 1 and 11 but fail to teach that the lozenge comprises urea. Majeti et al. cure this deficiency.

Regarding claims 11, 14 and 26, Majeti et al. teach oral care compositions for whitening of teeth (abstract) wherein the composition may be a lozenge (claim 9). Majeti et al. further teach that the oral care composition may comprise urea peroxide present at 5.5% (column 19, example 4, IV G).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Tame-Said and Georgiades with those of Majeti et al. to incorporate urea peroxide as a whitening agent into the composition of Tame-Said containing a whitening agent. One would have been motivated to do so because MPEP 2144.06 states that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art" quoting *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding claims 27-29, Majeti et al. teach that the oral care composition may comprise urea peroxide as a bleaching agent from about 0.1% to about 20.0% (claim

13). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed ranges lie inside the range disclosed by Majeti et al. and are therefore *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-15 and 24-29 have been considered but are moot in view of the new ground(s) of rejection. In response to applicant's argument that Majeti identifies urea peroxide as a bleaching agent instead of a plaque acid buffer, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/Joanne Hama/
Primary Examiner, Art Unit 1632